

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of *Daucus carota* ssp. *carota* seed extract & Persian Medicine Life style modifications with Clomiphene citrate on spermograms of men with idiopathic infertility: a randomized controlled trial

Protocol summary

Study aim

Comparison of the effect of *Daucus carota* ssp. *carota* seed extract & Persian medicine life style modifications with Clomiphene citrate on spermograms of men with idiopathic infertility: a randomized controlled trial

Design

Randomized controlled clinical trial with parallel groups, double-blind, phase 3 on 96 patients. Randomization was performed by block method

Settings and conduct

The study is performed on infertile and eligible men who are referred to the Nahal Infertility Clinic of Sayad Shirazi Center in Gorgan. *Daucus carota* seed extract capsules and clomiphene tablets are prepared and then enclosed in opac boxes to hide the allocation, which has nothing to do with this research. Which is provided to the research samples based on the table of random numbers created. The list of codes is confidential and is kept confidential until the data is analyzed. In this study, the researcher and the subjects will not know the contents of the packages.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men aged 20-50 years with idiopathic infertility (oligoasthenotratospermia), with normal hormonal tests and $BMI \leq 30 \text{ kg/m}^2$ who have agreed to be included in the study and have been visited and referred by a urologist Exclusion criteria: Includes any disorder or medication that indicates secondary infertility

Intervention groups

A = Receiving clomiphene tablets (1 tablet of 50 mg per day) B = Receiving clomiphene tablets and *Daucus carota* seed extract capsules (6 capsules of 700 mg per day - divided to three doses) C = Receiving clomiphene tablets and lifestyle modifications of Iranian medicine D = Receiving clomiphene tablets and capsules of *Daucus carota* seed extract with lifestyle modifications of Iranian

medicine The intervention will be performed in all groups for three months

Main outcome variables

Semen volume Sperm count Sperm movement Sperm morphology Sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210911052430N1**

Registration date: **2021-12-18, 1400/09/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-18, 1400/09/27**

Update count: **0**

Registration date

2021-12-18, 1400/09/27

Registrant information

Name

Sayed abolhasan Mousavi khorshidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3254 5182

Email address

mousavi.abolhasan@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-11, 1400/09/20

Expected recruitment end date

2023-12-11, 1402/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of *Daucus carota* ssp. *carota* seed extract & Persian Medicine Life style modifications with Clomiphene citrate on spermograms of men with idiopathic infertility: a randomized controlled trial

Public title

The effect of *Daucus carota* spp. *carota* seed extract & Persian Medicine Life style modifications on spermograms of men with idiopathic infertility

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Men 20-50 years with at least one year of idiopathic infertility disorder 2. Existence of at least one of the three criteria related to sperm disorder (number - motility - morphology) - Existence of idiopathic oligospermia disorder according to WHO criteria (Existence of sperm count less than 15 million per ml and total less than 39 million in semen It is called oligospermia) - Presence of idiopathic stenospemia according to WHO criteria (if the percentage of sperm with normal motility in semen is less than 40% is called stenospemia). Has a normal morphology in semen less than 4% is called teratospemia) 3. Patients with varicocele who has been 6 month since their surgery and have not been able to conceive 4. Normal testosterone, serum gonadotropins and prolactin 5. Normal thyroid hormones (no hypo or hypothyroidism) 6. BMI ≤ 30kg/m² 7. Satisfaction of the patient

Exclusion criteria:

1- Severe oligospermia or azoospermia (less than 5 million sperm per milliliter) 2- History of epididymitis, prostatitis, trauma, testicular torsion, inguinal scrotal surgery 3- Pretesticular disorders such as endocrine diseases (hyperprolactinemia, congenital adrenal hyperplasia ...) 4- Known Testicular disorders such as varicocele or orchitis or cryptorchidism 5- Known post testicular disorders such as mechanical obstruction, impaired egg transfer or functional obstruction, vasectomy, etc. 6- History of taking anti-metabolites and alkylators 7- History of cancer and chemotherapy and radiotherapy treatments 8- Having chronic diseases such as diabetes and cardiovascular disorders 9- Infection of the genital tract 10- Taking cytotoxic, immunosuppressive, androgen or anti-androgen drugs and alcohol or opium addiction 11- Having liver failure 12- Having kidney failure 13- History of receiving medicine for infertility treatment in the last three months 14- History of receiving drugs affecting semen in the last three months

Age

From **20 years** old to **50 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Random block allocation: For random allocation using blocks of 8, according to the number of samples, 12 blocks of 8 should be generated. For this purpose, from among possible 8-blocks, the number of which is 2520, based on uniform random selection, a random sequence obtained from 12 blocks of 8 was produced as follows: BADABCCD, ACDABBCD, AABCDBCD, ABDCACBD, BACDABCD, C ABDCABD, ABDCACBD, DABCDABC, CABDABCD, BADCACBD, CBABDACD, DABCACBD According to the above block, 96 envelopes are prepared and in each envelope, according to the table below, we put the letters D, C, B, A and number the envelopes from 1 to 96. The person delivering the envelopes to the patients does not know what is inside, in addition to the patient, the prescriber also does not know how to allocate patients. Patients fit the letter inside the envelope, they are in the desired group according to the following division. A = Receiving clomiphene tablets B = Receiving clomiphene tablets and *Daucus carota* seed extract capsules C = Receiving clomiphene tablets and lifestyle modifications of persian medicine D = Receiving clomiphene tablets and *Daucus carota* seed extract capsuls with lifestyle modifications of persian medicine The number of each patient in statistical examinations will be the same as the envelope number.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person delivering the envelopes to the patients does not know what is inside. Therefore, in addition to the patient, the prescriber also does not know how to allocate patients. Patients fit the letter inside the envelope, they are in the desired group according to the following division. A = Receiving clomiphene tablets B = Receiving clomiphene tablets and *Daucus carota* seed extract capsules C = Receiving clomiphene tablets and lifestyle modifications of persian medicine D = Receiving clomiphene tablets and *Daucus carota* seed extract capsuls with lifestyle modifications of persain medicine The number of each patient in statistical examinations will be the same as the envelope number.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan University of Medical Science

Street address

Hyrkan Boulevard - at the beginning of Shast Kola Road - Falsafi complex

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2021-12-06, 1400/09/15

Ethics committee reference number

IR.GOUMS.REC.1400.319

Health conditions studied

1

Description of health condition studied

Idiopathic Male Infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

Mean semen volume (cc)

Timepoint

Beginning and end of the study

Method of measurement

Use a pipette or calibrated tube

2

Description

Mean sperm count per milliliter of semen

Timepoint

Beginning and end of the study

Method of measurement

Sperm analyzer and neobar slide

3

Description

Mean percentage of motile sperms

Timepoint

Beginning and end of the study

Method of measurement

Sperm analyzer device and simple slide

4

Description

Mean sperm percentage with normal morphology

Timepoint

Beginning and end of the study

Method of measurement

Sperm analyzer device and simple slide

5

Description

Sexual function

Timepoint

Beginning and end of the study

Method of measurement

Men's Sexual Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Group 1: Receiving clomiphene citrate tablets - Iran Hormone company (1 tablet of 50 mg per day) - for three months

Category

Treatment - Drugs

2

Description

Intervention group: Group 2: Receiving clomiphene citrate tablets - Iran Hormone company (1 tablet of 50 mg per day) and Daucus carota seed extract capsules - Golestan University of Medical Science (6 capsules of 700 mg per day - divided to three doses) - for three months

Category

Treatment - Drugs

3

Description

Intervention group: Group 3: Receiving clomiphene citrate tablets - Iran Hormone company (1 tablet of 50 mg per day) and lifestyle modifications of persian medicine - three months

Category

Treatment - Drugs

4

Description

Intervention group: Group 4: Receiving clomiphene citrate tablets - Iran Hormone company (1 tablet of 50

mg per day) and *Daucus carota* seed extract capsules - Golestan University of Medical Science (6 capsules of 700 mg per day - divided to three doses) along with lifestyle modifications of Persian medicine - for three months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sayad Shirazi Educational - Medical Center of Gorgan

Full name of responsible person

Alireza Norouzi

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Sayad Shirazi Boulevard

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Golestan

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Phone

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Email

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Web page address

https://goums.ac.ir/index.php?slc_lang=fa&sid=78

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Abdorrezza Fazel

Street address

Hirkan Boulevard

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Golestan

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Email

Ravabetoomoomi@goums.ac.ir

Web page address

<https://goums.ac.ir/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Gorgan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Sayed Abolhasan Mousavi Khorshidi

Position

Ph.D Candidate of Persian Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Sayed Abolhasan Mousavi Khorshidi

Position

Ph.D Candidate of Persian Medicine

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Sayed Abolhasan Mousavi khorshidi

Position

Ph.D Candidate of Persian Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street addressThe beginning of Minagol 7 - Pol building - Unit 1 -
Mousavi Khorshidi house**City**

Gorgan

Province

Golestan

Postal code**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available